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SMITH PATENT CONSULTING CONSULTING, LLC
3309 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,869	KANDIL, OSAMA	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-8,12-14,16,17 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11,15,18-21 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Sheets (3)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed on January 08, 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Copies of several Non-Patent Literature cited on the IDS filed on January 08, 2008 were not included with the application and therefore these citations have not been considered.

Response to Amendment

This Office Action is in response to the amendment submitted on 01/08/2008. Claims 1-29 are pending in the applications, with claims 1-8, 11-14, 16-17, and 22-25 having being withdrawn in the response filed on 08/10/07. Accordingly, claims 9-11, 15, 18-21, and 26-29 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Examiner further acknowledges amendment of claim 9 and withdrawal of claim 11. Consequently, the scope of enablement rejection for the treatment of all skin disorders under 35 U.S. C. 112, first paragraph has been withdrawn.

Applicant's argument with respect to the term "prevention" has been considered but is not found persuasive. While applicant provided a definition of the term prevention in the specification and referred to wikipedia for a medical definition, the term "prevention" is still regarded as an absolute term signifying complete and total hindrance of a disease. Additionally, example 17 in the specification, proposes the prevention of an asthmatic effect by pre-injecting guinea pigs with the polyunsaturated fatty acid fraction of *Nigella sativa L.*, inducing asthma attack through exposure to histamine and then evaluating the protective effect while the polyunsaturated fatty acid fraction is still lingering in the system of the guinea pigs; however, such treatment is considered as a preventative treatment which is contrastingly different from prevention of asthma. True prevention would entail administering a particular preventive dosage amount of polyunsaturated fatty acid fraction, and waiting for a specific period of time to examine the protective effect long after the polyunsaturated fatty acid fraction has completely diminished from the system of the guinea pigs. Moreover, the specification fails to provide information as to how long does the preventive effect last and the exact preventive amount of polyunsaturated fatty acid fraction that is needed. Finally, there is no information of record that would allow the skilled artisan to practice the instant invention in preventing skin conditions without undue experimentation. As a result, the rejection of claims 9-11 and 26-29 under 35 U.S.C. 112, 1rst paragraph is still maintained.

Applicant's contention that Ahmad in view of Berg does not teach a method of treating skin diseases is acknowledged but is not found persuasive. Ahmad et al. teaches that members of the family Ranunculaceae are useful for the treatment of skin diseases and immunological disorders (see pg. 3, paragraph 0018-0019). Importantly, Ahmad et al. teaches that Nigella sativa is a member of the Ranunculaceae family (paragraph 0019-0020) supporting the notion that Nigella sativa can be used for treating skin disease as Ahmad et al. teaches the use of botanicals of its members useful for treating skin diseases. Also, Ahmad et al. teaches topical administration of its composition where such composition can be formulated as a hydrogel (i.e. semi-solid form paragraph 0092) and contains Nigella sativa extracts which necessarily contains the polyunsaturated fraction not free of sterol or volatile oils or glyceryl esters in a volume of no less than 20% by weight/volume (see pg. 3, paragraph 0024 and example 1). As for Berg, he teaches that diaper rash is a particular type of skin disease. Thus, it would have been obvious to one of ordinary skill in the art to use Nigella sativa, a member of the Ranunculaceae, for the treatment of diaper rash since Ahmad teaches that members of Ranunculaceae can be used for the treatment of skin diseases and given that Berg teaches that diaper rash is a skin disease. As a result, Ahmad et al. in view of Berg necessarily meets the limitation of claims 9, 11, and 26 as previously presented.

Applicant's argument that the modification of the prior art references (Ahmad in view of Berg) would be unobvious and inoperable is acknowledged but is found non-

persuasive. Given that Ahmad et al. teaches Nigella sativa as a member of the Ranunculaceae family and given that Ahmad et al. also suggests the use of botanical members of Ranunculaceae as useful for treating skin diseases, one of ordinary skill would have been motivated to try disclosed members of Ranunculaceae as cited by Ahmad et al. to treat diaper rash, a type of skin disorder disclosed by Berg with the expectation of success since Ahmad et al. teaches that members of such family are useful for treating skin diseases.

Applicant's argument that Nickavar et al. fails to provide a motivation suggestion to formulate the Ahmad extract as a semi-solid composition suitable for topical administration and utilize it as a method of treating or preventing skin conditions is acknowledged and is found non-persuasive. Nickavar et al. was provided in further view of Ahmad and Berg to demonstrate that the polyunsaturated fraction contained in the extract of Ahmad et al. and designated by Nickavar et al. as fixed oil of *Nigella sativa L.* contains 23.4% octadecenoic acid (i.e. oleic acid) and 55.6% octadecadienoic acid (i.e. linoleic acid) and this meets the limitation of claims 28-29 as previously presented.

Applicant's argument Schlenk and Ali fails to provide a motivation suggestion to formulate the Ahmad extract as a semi-solid composition suitable for topical administration and utilize it as a method of treating or preventing skin conditions is acknowledged and is found non-persuasive. Schlenk et al. was provided in further view

of Ahmad and Berg to demonstrate that urea complex formation could be used for the separation of polyunsaturated fatty acid fraction devoid of sterol, volatile oils and glyceryl esters while Ali et al. was provided to demonstrate that the motivation to perform the urea complex formation was due to the presence of biological actives present in the polyunsaturated fatty acid fraction. Consequently, Schlenk and Ali necessarily meet the limitation of claim 27 as previously presented.

In view of applicant's amendment, the 112 1rst scope of enablement rejection (for treating all skin conditions) is withdrawn and the following Obvious Double Patenting, 112 1rst enablement, and modified 103 (a) Non-Final rejections are being made.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 11, 15, and 26-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 11, and 23-24 of copending Application No. 10/809856 (hereinafter Kandil US Patent Application No. '856). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating skin infection in a patient in need thereof comprising administering a lipid fraction extracted from *Nigella sativa L. seeds* and a pharmaceutically acceptable carrier. The claimed invention and co-pending application Kandil '856 are rendered obvious over another as the claimed invention teaches a broad genus of skin conditions arising from bacterial infections with the subgenus polyunsaturated fatty acid fraction of

Nigella sativa L. seeds whereas Kandil '856 teaches a subgenus of pyogenic skin infections (i.e. specific bacterial skin infections) with a broad genus of lipid fraction of *Nigella sativa L.* seeds. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/809856.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 9, 11, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 and 11 of copending Application No. 12/043052 (hereinafter Kandil US Patent Application No. '052). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating skin infection in a patient in need thereof comprising administering a lipid fraction extracted from *Nigella sativa L. seeds* and a pharmaceutically acceptable carrier. The claimed invention and co-pending application Kandil '052 are rendered obvious over another as the claimed invention teaches a broad genus of skin conditions arising from bacterial infections with the subgenus polyunsaturated fatty acid fraction of *Nigella sativa L. seeds* whereas Kandil '052 teaches a subgenus of pyogenic skin infections (i.e. specific bacterial skin infections) with a broad genus of lipid fraction of *Nigella sativa L.* seeds. Thus, the aforementioned claims of the instant application are

substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 12/043052.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11, 15, 18-21 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation, does not reasonably provide enablement for a method to prevent a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Importantly, given that the term “prevention” implies an absolute term, it is assumed that no known disease can be absolutely prevented at this time or completely hindered. For example, applicant does not reasonably provide enablement for a method to prevent allergic reaction. Rather applicant demonstrates in

example 17 of the specification a preventative treatment after exposure to histamine while no specific guidance is provided as to how long the prophylactic treatment actually lasts. Additionally, the application does not enable any person skilled in the art to use the invention to prevent skin conditions arising from bacterial infection, fungal infection or inflammation.

The instant claims are drawn to a method of treating or preventing a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation comprising topically administering an effective amount of a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa L.* seeds and a pharmaceutically acceptable carrier. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention as claimed.

Attention is directed to *In reWands,* 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman,* 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1. <u>The nature of the invention, state and predictability of the art, and relative</u>

skill level

The invention relates to a method of treating or preventing a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation comprising topically administering an effective amount of a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa L.* seeds and a pharmaceutically acceptable carrier. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites the above fact where preventive measures against a skin condition arising from bacterial infection, fungal infection, or inflammation cannot be absolutely prevented.

2. The breadth of the claims

Since the instant specification provides no limiting definition of the term "prevention", the examiner will adopt the broadest reasonable interpretation for same. Webster's Ninth New Collegiate Dictionary defines "prevention" as "to keep from happening or existing", i.e., to completely eradicate.

The claims are thus very broad insofar as they recite the "prevention" of skin conditions arising from inflammation, fungal infection, bacterial infection or allergic reaction, i.e., the complete eradication of same. While such "prevention" might theoretically be possible under strictly controlled laboratory conditions, as a practical

matter it is nearly impossible to achieve in the "real world" in which patients live.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for a method for preventing skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation comprising topically administering an effective amount of a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa L.* seeds and a pharmaceutically acceptable carrier. In fact, applicant only provided guidance for a preventative treatment of a skin condition arising from inflammation.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed polyunsaturated fatty acid fraction could be predictably used to prevent skin conditions arising from inflammation, fungal infection, bacterial infection, or allergic reaction as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation in order to determine if said polyunsaturated fatty acid

fraction claimed by applicant can prevent or forever hinder the appearance of skin conditions arising from inflammation, fungal infection, bacterial infection, or allergic reaction, with no assurance of success.

Genentech, 108 F.3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

5. Suggested alternative language

Since the term "treating" is inclusive of various administrative timing schemes and thus provides adequate coverage for all reasonably successful therapies (prophylactic or active), the examiner recommends deleting the term "preventing" and simply reciting "treating" instead.

Therefore, a method for preventing a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation comprising topically administering an effective amount of a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa L.* seeds and a pharmaceutically acceptable carrier is not considered to be enabled by the instant specification.

The claims are examined herein for a method of treating a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation comprising topically administering an effective amount of a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa L.* seeds and a pharmaceutically acceptable carrier.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

As for the term "consisting essentially of" limitation in claims 15 and 28, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Claims 9-11, 15, 18-21 and 26 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1, previously submitted) in view of Berg (Advances in Dermatology, 1988, pg. 75-98, previously submitted).

Ahmad et al. teaches that many members of the family Ranunculaceae can be used for treatment of a variety of conditions including skin diseases (see pg. 3, paragraph 0019). Ahmad et al. also teaches novel compositions for botanicals that are members of the Ranunculaceae and extracts derived from these plants. The compositions comprise botanicals from members of the Ranunculaceae including Nigella sativa or extracts thereof along with a pharmaceutically acceptable carrier (see pg. 3, paragraph 0019-0020). The compositions of Ahmad et al. can be administered topically (see pg. 1, paragraphs 001, 0019 and 0029), formulated as a semi-solid composition (see pg. 10, paragraph 0082; formulated as a hydrogel which is a semi-solid composition; paragraphs 0087 and 0092) and can contain emulsifying agents (instant claim 21, paragraph 0068), surfactants (i.e. stabilizing agents; instant claim 21, paragraph 0085), and preservatives (instant claim 21; see pg. 8, paragraph 0065). Ahmad et al. exemplified its composition containing *Nigella sativa L.* where Nigella seeds, leaves, flowers and stems are extracted and the liquid extract is concentrated and the vegetative materials are discarded. Consequently, this crude extraction necessarily contains the polyunsaturated fatty acid fraction (see pg. 14-15, paragraph 00127-00129). Importantly, the botanical ingredients of Nigella sativa extracts are in a concentration of not less than 20% weight by volume and this necessarily suggests that

the polyunsaturated fatty acid fraction is in an amount of no less than 20% and this necessarily meets the limitation of claims 18-20 and 26 (instant claims 18-20 and 26; see abstract and paragraph 0024 and 00129).

Ahmad et al. does not specifically teach a method of treating a particular skin condition such as diaper rash (the elected species) or skin conditions arising from bacterial infection, fungal infection, allergic reaction or inflammation.

Berg, however, teaches that common diaper dermatitis (i.e. diaper rash) entails a group of inflammatory disorders that affect the skin covered by diapers (i.e. instant claim 11, see pg. 75, paragraph 01). Furthermore, Berg teaches that many dermatological conditions can occur in the diaper area including skin disorders such as seborrheic dermatitis (non-elected species of claim 11), atopic dermatitis (non-elected species of claim 11), impetigo (bacterial skin infection, i.e. skin infection arising from bacterial skin infection; instant claim 9) and microbial infections (which entails bacterial, fungal infections, etc…; instant claim 9) and this necessarily meets the limitation of claims 9 and 11 (see pg. 76, section of Dermatoses in the Diaper area).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the method of Ahmad et al. to treat diaper rash with the knowledge of diaper rash as a skin disease provided by Berg given that Ahmad et al. teaches a method of treating skin diseases using members of Ranunculaceae such as

Nigella sativa and given that Berg teaches that diaper rash is a particular type of skin disease. Given that Ahmad teaches that members of the family Ranunculaceae are useful for treating skin diseases and given that *Nigella sativa L.* is a member of the aforementioned family and its crude extract necessarily contains the polyunsaturated fatty fraction, and Berg discloses that diaper rash is a type of skin disease, one of ordinary skill would have been motivated to utilize the composition of Ahmad et al. given the disclosure of Ahmad and Berg with the expectation of providing a method that is not only efficient in treating diaper rash but also a method that is useful in treating intertrigo, dermatitis, bacterial and fungal infections affecting the skin.

Regarding the skin moisturizing, revitalizing and analgesic effects as recited in claim 10, it is considered that one of ordinary skill in the art at the time of the invention was made would have found it obvious to conclude that the method of treating a skin condition using the extracted composition of Ahmad et al. would possess the same sensory and pharmacokinetic profiles as that disclosed by applicant since Ahmad et al. uses the same exact *Nigella sativa L.* seeds and such characteristics are properties of Nigella sativa L. seeds and a property is inseparable from the parent compound.

It is noted that In re Best,195 USPQ 430, and In re Fitzgerald, 205 USPQ 594, discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the

applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1, previously submitted) in view of Berg (Advances in Dermatology, 1988, pg. 75-98, previously submitted) as applied to claims 9-11, 15, 18-21 and 26 above and in further view of Schlenk et al. (J. of Amer. Chem. Soc. 1950,Vol. 72, pg. 5001-5004, previously submitted).

The Ahmad and Berg references are as discussed above and incorporated by reference herein. However, Ahmad and Berg do not address a polyunsaturated fatty acid fraction of Nigella L. sativa seeds free of saturated fatty acids, sterols, volatile oils and glyceryl esters.

Schlenk et al. teaches a method of extracting polyunsaturated acid fraction from saturated fatty acids using a urea complex to yield a polyunsaturated fatty acid fraction devoid of saturated fatty acids and glyceryl esters and highly enriched (instant claim 27). Schlenk et al. further teaches that separation of the saturated from the polyunsaturated fatty acid fraction leads to enrichment of each type of fatty acid fraction from natural oils (see pg. 5003, paragraph 2).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the composition of Ahmad et al. with the method of Schlenk et al. since Schlenk et al. teaches that urea complexes leads to the enrichment of saturated and polyunsaturated fatty acid fractions. Given that Ahmad teaches that members of the family Ranunculaceae are useful for treating skin diseases and given that *Nigella sativa L.* is a member of the aforementioned family and its crude extract necessarily contains the polyunsaturated fatty fraction, and Berg discloses that diaper rash is a type of skin disease, and Schlenk et al. teaches that urea complexes can lead to enrichment of saturated and polyunsaturated fatty acids from natural oils, one of ordinary skill would have been motivated to utilize the composition of Ahmad et al. to treat diaper rash given the disclosure of Ahmad and Berg and enrich the composition with either saturated fatty acids or polyunsaturated fatty acids as disclosed by Schlenk et al. with the expectation of providing a composition that is highly enriched in saturated or unsaturated fatty acids and useful in treating diaper rash.

Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1, previously submitted) in view of Berg (Advances in Dermatology, 1988, pg. 75-98, previously submitted) as applied to claims 9-11, 15, 18-21 and 26 above and in further view of Nickavar et al. (Z. Naturforsch. 2003, Vol. 58c, pg. 629-631, previously submitted).

The Ahmad and Berg references are as discussed above and incorporated by reference herein. However, Ahmad and Berg do not address the particular components of the polyunsaturated fatty acid fraction.

Nickavar et al. teaches that the chemical composition of the fixed oil (i.e. saponified fraction-see table 1 of applicant) of *Nigella sativa L*. comprises 23.4% of oleic acid (i.e. octadecenoic acid) and 55.6% of linoleic acid (i.e. octadecadienoic acid)(instant claims 28-29). Nickavar has been provided to demonstrate that the polyunsaturated fatty acid fraction of Nigella sativa L extract utilized by Ahmad necessarily contains octadecenoic acid and octadecadienoic acid in the aforementioned ranges and this necessarily meets the limitation of claims 28-29.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the composition of Ahmad as evidenced by Nickavar et al. (given the specific ingredients contained in the polyunsaturated fatty acid fraction disclosed by Nickavar) to treat diaper rash in view of the knowledge of diaper rash as a skin disease provided by Berg given that Ahmad et al. teaches a method of treating skin diseases using members of Ranunculaceae such as Nigella sativa and given that Berg teaches that diaper rash is a type of skin disease. Since Ahmad teaches that members of the family Ranunculaceae are useful for treating skin diseases and given that *Nigella sativa L.* is a member of the aforementioned family that contains 23.4% of octadecenoic acid and 55.6% of octadecadienoic acid of polyunsaturated fatty fraction (as taught by

Nickavar et al.), and Berg discloses that diaper rash is a type of skin disease, one of ordinary skill would have been motivated to utilize the composition of Ahmad et al. given the disclosure of Ahmad and Nickavar to treat diaper rash given the disclosure of Berg with the expectation of providing a method that is not only efficient in treating diaper rash but also useful in treating various skin disorders including intertrigo, dermatitis, bacterial and fungal infections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

03/18/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617